



DOCKET NO.: TJU-2444

1642  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Scott A. Waldman

Confirmation No.: 8378

Application No.: 09/724,983

Group Art Unit: 1642

Filing Date: November 28, 2000

Examiner: Gary B. Nickol

For: ST RECEPTOR BINDING COMPOUNDS AND METHODS OF USING THE SAME

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DATE OF DEPOSIT:

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*Elizabeth A. McLoud*

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

COMMUNICATION REGARDING  
INFORMATION DISCLOSURE STATEMENT

- ☒ In the Office Action dated December 31, 2002, the Examiner indicated that certain references were not considered; the Examiner has requested additional copies of references that were previously cited by or submitted to the Patent and Trademark Office. Enclosed are copies of references AA-GH (with the exception of AB, AE, AK and BY which are voluminous and CO which is a duplicate of CN) that were listed on the PTO Form 1449 originally filed May 15, 2001, a copy of which is attached to this communication. A copy of the date-stamped postcard dated May 17, 2001 is also attached. Accordingly, Applicants believe no fee is due for providing copies of these references.

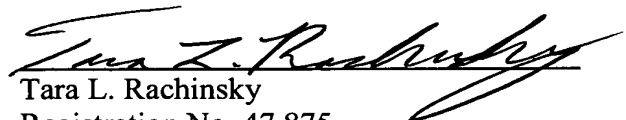
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- ☒ It is respectfully requested that the Examiner initial and date the attached pages of the 1449 confirming that the references citing thereon have been considered. A clean copy of the PTO-1449 is enclosed for the Examiner's convenience.

The Commissioner is authorized to charge payment of any fees associated with this communication and to refund any overpayment associated with this communication or during the pendency of this application to deposit account 23-3050.

Date: *July 24, 2003*

  
Tara L. Rachinsky  
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**Paper:** Information Disclosure Statement (in duplicate) w/ first class stamp; USPTO-1449 (13 pages); 164 references cited/ 1 reference submitted; return postcard

**Applicant(s) :** Scott A. Waldman

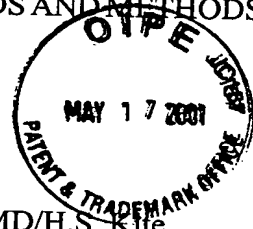
**Title:** ST RECEPTOR BINDING COMPOUNDS AND METHODS OF USING THE SAME

**Serial No.:** 09/724,983

**Filed:** November 28, 2000

**Docket No.:** TJU-2444

**Date Sent:** May 15, 2001



MD/H.S. Kite



DOCKET NO.: TJU-2444

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Scott A. Waldman

Serial No.: 09/724,983

Group Art Unit: Not Yet Assigned

Filing Date: November 28, 2000

Examiner: Not Yet Assigned

For: **ST RECEPTOR BINDING COMPOUNDS AND METHODS OF USING  
THE SAME**

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TYPED NAME: Mark DeLuca  
REGISTRATION NO.: 33,229

Assistant Commissioner for Patents  
Washington DC 20231

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).



In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required, or before the mailing date of a first office action after the filing of request for continued examination under §1.114.

- ☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐the first or ☐second After Final Submission, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or before an action that otherwise closes prosecution in the application, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); and the submission fee of \$180.00 as set forth in §1.17(p).
- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☒ In view of the voluminous nature of references **AB, AK, and BY**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.



In accordance with §1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. §120 have been made in the instant application:



Copies of references **AA, BU, CC, CN, EA-ET, FM-GG** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. **08/583,447**, filed **January 5, 1996**; copies of references **AH-AJ, AL-BT, BV-BX, CA-CB, CD-CM, CO-CS, DJ-DZ, EU-EY, FE-FF and FH-FL** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. **08/635,930**, filed **April 26, 1996**; copies of references **BZ, CT-DI, and EZ-FD** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. **08/468,449**, filed **June 6, 1995**; copies of references **AC-AG** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. **09/138,237**, filed **August 21, 1998**.



If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**DOCKET NO.: TJU-2444**

**- 4 -**

**PATENT**

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050.

This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date: 5 - 15 - 01



**Mark DeLuca**

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<b>Form PTO-1449 Modified</b> U.S. Department of Commerce Patent and Trademark Office (Use several sheets if necessary)		Docket No. <b>TJU-2444</b>	Serial No. <b>09,724,983</b>
		Applicant <b>Scott A. Waldman</b>	
		Filing Date <b>November 28, 2000</b>	Group <b>Not Yet Assigned</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>AA</b>	Bremer, K.H., et al., "Safety and efficacy of radiopharmaceuticals," Kristensen, K., et al. (eds.), Martinus Nijhoff, Dordrecht, the Netherlands, 1987, 43-50	
*	<b>AB</b>	Dayhof, <i>Nat. Biomed. Res. Found.</i> , 1978, Washington, D.C., 5, Supp. 3	
	<b>AC</b>	Hugues, M., et al., "Affinity purification of functional receptors for escherichia coli heat-stable enterotoxin from rat intestine," <i>Biochemistry</i> , 1992, 31, 12-16	
	<b>AD</b>	Kent, and Clark-Lewis in Synthetic peptides in biology and medicine, Alitalo, K., et al., (eds.), <i>Science Publishers, Amsterdam</i> , 1985, 295-358	
	<b>AE</b>	The Proteins, Vol. II, 3 <sup>rd</sup> Ed., pages 105-237, Neurath, H., et al. (eds.), <i>Academic press, New York, NY</i> , 1976	
	<b>AF</b>	Paxton, R.J., et al., "High-specific-activity 111 <sup>In</sup> -labeled anticarcinoembryonic antigen monoclonal antibody: improved method for the synthesis of diethylenetriaminepentaacetic acid conjugates," <i>Cancer Res.</i> , 1985, 45, 5694-5699	
	<b>AG</b>	Eildon, S.P., "Cytotoxicity and viability assays," <i>Animal Cell Culture: A Practical Approach</i> , Freshney, R.I. (Ed.), <i>IRL Press, Oxford</i> , 1986, 183-216	
	<b>AH</b>	Almenoff, et al., "Ligand-based histochemical localization and capture of cells expressing heat-stable enterotoxin receptors," <i>Molecular Microbiology</i> , 1993, 8, 865-873	
	<b>AI</b>	Bjorn, et al., "Antibody-pseudomonas exotoxin A conjugates cytotoxic to human breast cancer cells in vitor," <i>Cancer Research</i> , 1986, 46, 3262-3267	
	<b>AJ</b>	Bjorn, et al., "Evaluation of monoclonal antibodies for the development of breast cancer immunotoxins," <i>Cancer Research</i> , 1985, 45, 1214-1221	
*	<b>AK</b>	Bodansky, et al., "Peptide synthesis," John Wiley and Sons, 2d Ed., 1976	
	<b>AL</b>	Burgess, et al., "Biological evaluation of a methanol-soluble, heat-stable escherichia coli enterotoxin in infant mice, pigs, rabbits and calves," <i>Infection and Immunity</i> , 1978, 21, 526-531	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

\* A copy of this reference will not be forwarded to the Patent Office since it is believed to be too voluminous to send and easily obtainable by the Examiner.



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List of Patent and Publications  
Cited by Applicant  
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U.S. Department of Commerce  
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Docket No.  
TJU-2444

Serial No.  
09,724,981

Applicant  
Scott A. Waldmann

Filing Date  
November 28, 2000

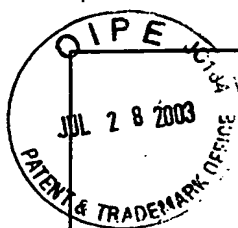
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AM	Cawley, et al., "Epidermal growth factor-toxin a chain conjugates: EGF-ricin A is a potent toxin while EGF-diphtheria fragment A is nontoxic," <i>Cell</i> , 1980, 22, 563-570
AN	Chan, et al., "Amino acid sequence of heat-stable enterotoxin produced by <i>escherichia coli</i> pathogenic for man," <i>J. Biol. Chem.</i> , 1981, 256, 7744-7746
AO	Chung, et al., "Enzymatically active peptide from the adenosine diphosphate-ribosylating toxin of <i>pseudomonas aeruginosa</i> ," <i>Infection and Immunity</i> , 1977, 16, 832-841
AP	Cumber, et al., "Preparation of antibody-toxin conjugates," <i>Methods in enzymology</i> , 1985, 112, 207-225
AQ	Currie, et al., "Guanylin: an endogenous activator of intestinal guanylate cyclase," <i>Proc. Natl. Acad. Sci. USA</i> , 1992, 89, 947-951
AR	Dreyfus, et al., "Chemical properties of heat-stable enterotoxins produced by enterotoxigenic <i>escherichia coli</i> of different host origins," <i>Infection and Immunity</i> , 1983, 42, 539-548
AS	Eckelman, et al., "Comparison of <sup>99m</sup> Tc and <sup>111</sup> in labeling of conjugated antibodies," <i>Nucl. Med. Biol.</i> , 1986, 13, 335-343
AT	Evans, et al., "Differences in the response of rabbit small intestine to heat-labile and heat-stable enterotoxins of <i>escherichia coli</i> ," <i>Infection and Immunity</i> , 1973, 7, 873-880
AU	Fitzgerald, et al., "Adenovirus-induced release of epidermal growth factor and <i>pseudomonas</i> toxin into the cytosol of KB cells during receptor-mediated endocytosis," <i>Cell</i> , 1983, 32, 607-617
AV	Fitzgerald, et al., "Construction of immunotoxins using <i>pseudomonas</i> exotoxin A," <i>Meth. In Enzymology</i> , 1987, 151, 139-145

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**Form PTO-1449 Modified**

List of Patent and Publications  
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Docket No.  
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Serial No.  
**09,724,983**

Applicant  
**Scott A. Waldmann**

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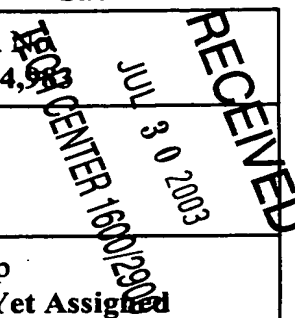
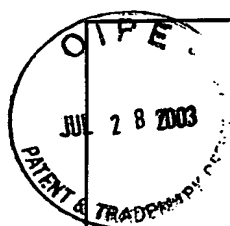
**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

<b>AW</b>	Giannella, et al., "Development of a radioimmunoassay for escherichia coli heat-stable enterotoxin: comparison with the suckling mouse bioassay," <i>Infection and Immunity</i> , 1981, 33, 186-192
<b>AX</b>	Gros, O., "Biochemical aspects of immunotoxin preparation," <i>J. Immunol. Meth.</i> , 1985, 81, 283-297
<b>AY</b>	Gyles, C.F., "Discussion: heat-labile and heat-stable forms of the enterotoxin from E. coli strains enteropathogenic for pigs," <i>Ann. N.Y. Acad. Sci.</i> , 1979, 16, 314-321
<b>AZ</b>	Hakki, et al., "Solubilization and characterization of functionally coupled escherichia coli heat-stable toxin receptors and particulate guanylate cyclase associated with the cytoskeleton compartment of intestinal membranes," <i>Int. J. Biochem.</i> , 1993, 25, 557-566
<b>BA</b>	Hugues, et al., "Identification and characterization of a new family of high-affinity receptors for escherichia coli heat-stable enterotoxin in rat intestinal membranes," <i>Biochemistry</i> , 1991, 30, 10738-10745
<b>BB</b>	Humm, et al., "Dosimetric aspects of radiolabeled antibodies for tumor therapy", <i>J. Nuclear Med.</i> , 1986, 27, 1490-1497
<b>BC</b>	Klipstein, et al., "Development of a vaccine of cross-linked heat-stable and heat-labile enterotoxins that protects against escherichia coli producing either enterotoxin", <i>Infection and Immunity</i> , 1982, 37, 550-557
<b>BD</b>	Krejcarek, et al., "Covalent attachment of chelating groups to macromolecules", <i>Biochem. And Biophy. Res. Commun.</i> , 1977, 77, 581-585
<b>BE</b>	Kwok, "Calculation of radiation doses for nonuniformly distributed $\beta$ and $\gamma$ radionuclides in soft tissue", <i>Med. Phys.</i> , 1985, 12, 405-412
<b>BF</b>	Leonard, et al., "Kinetics of protein synthesis inactivation in human T-lymphocytes by selective monoclonal antibody-ricin conjugates", <i>Cancer Res.</i> , 1985, 45, 5263-5269
<b>BG</b>	Magerstadt, M., "Antibody conjugates and malignant disease", Boca Raton: CRC Press, 1991, 110-152

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**09,724,983**List of Patent and Publications  
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**Scott A. Waldmann**U.S. Department of Commerce  
Patent and Trademark OfficeFiling Date  
**November 28, 2000**Group  
**Not Yet Assigned****OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

<b>BH</b>	Masuho, et al., "Importance of the antigen-binding valency and the nature of the cross-linking bond in ricin a-chain conjugates with antibody," <i>J. Biochem.</i> , <b>1982</b> , 91, 1583-1591
<b>BI</b>	Merrifield, "Solid phase peptide synthesis, I. The synthesis of a tetrapeptide," <i>J. Am. Chem. Society</i> , <b>1963</b> , 15, 2149-2154
<b>BJ</b>	Michel, et al., "Fluorescence studies of nucleotides binding to diphtheria toxin and its fragment A," <i>Biochimica et Biophysica Acta</i> , <b>1974</b> , 365, 15-27
<b>BK</b>	Moseley, et al., "Isolation and nucleotide sequence determination of a gene encoding a heat-stable enterotoxin of escherichia coli," <i>Infect. And Immun.</i> , <b>1983</b> , 39, 1167-1174
<b>BL</b>	Okamoto, et al., "Substitutions of cysteine residues of escherichia coli heat-stable enterotoxin by oligonucleotide-directed mutagenesis," <i>Infect. And Immun.</i> , <b>1987</b> , 55, 2121-2125
<b>BM</b>	Richardson, et al., "Astatine ( <sup>211</sup> At) as a therapeutic radionuclide. The plasma: blood cell distribution in vitro," <i>Nucl. Med. Biol.</i> , <b>1986</b> , 13, 583-584
<b>BN</b>	Sack, "Human diarrheal disease caused by enterotoxigenic escherichia coli," <i>Ann. Rev. Microbiol.</i> , <b>1975</b> , 29, 333-353
<b>BO</b>	Shimonishi, et al., "Mode of disulfide bond formation of a heat-stable enterotoxin (St <sub>h</sub> ) produced by a human strain of enterotoxigenic escherichia coli," <i>FEBS</i> , <b>1987</b> , 215, 165-170
<b>BP</b>	So, et al., "Nucleotide sequence of the bacterial transposon Tn1681 encoding a heat-stable (ST) toxin and its identification in enterotoxigenic escherichia coli strains," <i>Proc. Natl. Acad. Sci.</i> , <b>1980</b> , 77, 4011-4015
<b>BQ</b>	Spitler, et al., "Therapy of patients with malignant melanoma using a monoclonal antimelanoma antibody-ricin A chain immunotoxin," <i>Cancer Res.</i> , <b>1987</b> , 1717-1723
<b>BR</b>	Steinstraßer, et al., "Selection of nuclides for immunoscintigraphy/immunotherapy," <i>J. Nucl. Med.</i> , <b>1988</b> , 5, 875
<b>BS</b>	Thompson, et al., "Biological and immunological characteristics of <sup>125</sup> I try escherichia coli heat-stable enterotoxin species purified by high-performance liquid chromatography," <i>Analytical Biochem.</i> , <b>1985</b> , 26-36

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List of Patent and Publications  
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U.S. Department of Commerce  
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**TJU-2444**

Serial No.  
**09,724,883**

Applicant  
**Scott A. Waldmann**

Filing Date  
**November 28, 2000**

Group  
**Not Yet Assigned**

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	<b>BT</b>	Thorpe, et al., "New coupling agents for the synthesis of immunotoxins containing a hindered disulfide bond with improved stability in vivo," <i>Cancer Research</i> , <b>1987</b> , 47, 5924-5931
	<b>BU</b>	Waldman, et al., "Influence of a glycine or proline substitution on the functional properties of a 14-amino-acid analog of escherichia coli heat-stable enterotoxin," <i>Infect. And Immun.</i> , <b>1989</b> , 57, 2420-2424
	<b>BV</b>	Wessels, et al., "Radionuclide selection and model absorbed dose calculations for radiolabeled tumor associated antibodies," <i>Med. Phys.</i> , <b>1984</b> , 11, 638-645
	<b>BW</b>	Worrell, et al., "Effect of linkage variation on pharmacokinetics of ricin A chain-antibody conjugates in normal rats," <i>Anti-Cancer Drug Design</i> , <b>1986</b> , 1, 179-188
	<b>BX</b>	Yoshimura, et al., "Essential structure for full enterotoxigenic activity of heat-stable enterotoxin produced by enterotoxigenic escherichia coli," <i>FEBS</i> , <b>1985</b> , 2232, Vol. 181, 138-142
*	<b>BY</b>	Barchel, et al., "Radioimaging and radiotherapy," New York, <b>1983</b>
	<b>BZ</b>	Farnz, et al., "The production of <sup>99m</sup> Tc-labeled conjugated antibodies using a cyclam-based bifunctional chelating agent," <i>J. Nucl. Med. Biol.</i> , <b>1987</b> , 14, 569-572
	<b>CA</b>	de Sauvage, F., et al., "Primary structure and functional expression of the human receptor for escherichia coli heat-stable enterotoxin," <i>J. Bio. Chem.</i> , <b>1991</b> , 266, 17912-17918
	<b>CB</b>	Corstens, et al., "Chemotactic peptides: new locomotion for imaging infection?," <i>J. Nucl. Med.</i> , <b>1991</b> , 32(3), 491-494
	<b>CC</b>	Fischman, et al., "A ticket to ride: peptide radiopharmaceuticals," <i>J. Nucl. Med.</i> , <b>1993</b> , 34, 2253-2263
	<b>CD</b>	Thompson, "Escherichia coli heat-stable enterotoxins and their receptors," <i>Pathol. Immunopathol. Res.</i> , <b>1987</b> , 6, 103-116
	<b>CE</b>	Cohen, M., et al., "Receptors for escherichia coli heat stable enterotoxin in human intestine and in a human intestinal cell line (Caco-2)," <i>J. Cellular Physiol.</i> , <b>1993</b> , 156, 138-144

\* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner.


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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	<b>CF</b>	Guarino, A., et al., "T <sup>84</sup> cell receptor binding and guanyl cyclase activation by escherichia coli heat-stable toxin," <i>Am. J. Physiol.</i> , <b>1987</b> , 253, (Gastrointest. Liver Physiol. 16): G775-780
	<b>CG</b>	Vaandrager, A., et al., "Atriopeptins and escherichia coli enterotoxin ST <sup>a</sup> have different sites of action in mammalian intestine," <i>Gastroenterology</i> , <b>1992</b> , 102(4), 1161-1169
	<b>CH</b>	Aitken, R. et al., "Recombinant enterotoxins as vaccines against <i>Escherichia coli</i> -mediated diarrhoea", <i>Vaccine</i> , <b>1993</b> , 11(2), 227-233
	<b>CI</b>	Chelly, J. et al., "Illegitimate transcription: Transcription of any gene in any cell type", <i>Proc. Natl. Acad. Sci. USA</i> , <b>1989</b> , 86, 2617-2621
	<b>CJ</b>	Chelly, J. et al., "Illegitimate Transcription: Application to the Analysis of Truncated Transcripts of the Dystrophin Gene in Nonmuscle Cultured Cells from Duchenne and Becker Patients", <i>J. Clin. Invest.</i> , <b>1991</b> , 88(4), 1161-1166
	<b>CK</b>	Cooper, D.N. et al., "Ectopic (Illegitimate) Transcription: New Possibilities for the Analysis and Diagnosis of Human Genetic Disease", <i>Ann. Med.</i> , <b>1994</b> , 26(1), 9-14
	<b>CL</b>	Field, M., "Role of Cyclic Nucleotides in Enterotoxic Diarrhea", <i>Mol. Cyclic Nucl. Res.</i> , <b>1980</b> , 12, 267-277
	<b>CM</b>	Giannella, R.A., "Pathogenesis of Acute Bacterial Diarrheal Disorders", <i>Ann. Rev. Med.</i> , <b>1981</b> , 32, 341-357
	<b>CN</b>	Kaplan, J.C. et al., "Illegitimate transcription: its use in the study of inherited disease", <i>Human Mutation</i> , <b>1992</b> , 1(5), 357-360 (Abstract only)
<i>Copy of CN</i>	<b>CO</b>	Kaplan, J.C. et al., "Illegitimate transcription: its use in the study of inherited disease", <i>Human Mutation</i> , <b>1992</b> , 1(5), 357-360 (Abstract only)
	<b>CP</b>	Negrier, C. et al., "Illegitimate transcription: its use for studying genetic abnormalities in lymphoblastoid cells from patients with Glanzmann thrombasthenia", <i>British J. Haematology</i> , <b>1998</b> , 100(1), 33-39

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**Form PTO-1449 Modified**Docket No.  
**TJU-2444**Serial No.  
**09,724,283**List of Patent and Publications  
Cited by Applicant  
(Use several sheets if necessary)Applicant  
**Scott A. Waldmann**U.S. Department of Commerce  
Patent and Trademark OfficeFiling Date  
**November 28, 2000**Group  
**Not Yet Assigned****OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	<b>CQ</b>	Rao, M.C. et al., "Enterotoxins and Anti-toxins: Enterotoxins and ion transport", <i>Biochem.</i> , <b>1984</b> , <i>12</i> , 177-180
	<b>CR</b>	Zippelius, A. et al., "Limitations of Reverse-Transcriptase Polymerase Chain Reaction Analyses for Detection of Micrometastatic Epithelial Cancer Cells in Bone Marrow", <i>J. Clin. Oncology</i> , <b>1997</b> , <i>15</i> (7), 2701-2708
	<b>CS</b>	PCT International Search Report dated August 7, <b>1997</b> , 1 page
	<b>CT</b>	Aimoto, S., et al., "Chemical synthesis of a highly potent and heat-stable analog of an enterotoxin produced by a human strain of enterotoxigenic escherichia coli," <i>Biochem. &amp; Biophys. Res. Comm.</i> , <b>1983</b> , <i>112</i> (1), 320-326
	<b>CU</b>	Carepick, B.W., et al., "The escherichia coli heat-stable enterotoxin is a long-lived superagonist of guanylin," <i>Infection &amp; Immunity</i> , <b>1993</b> , <i>61</i> (11), 4710-4715
	<b>CV</b>	Garipey, J., "Importance of disulfide bridges in the structure and activity of escherichia coli enterotoxin St1b," <i>Proc. Natl. Acad. Sci. USA</i> , <b>1987</b> , <i>84</i> , 8907-8911
	<b>CW</b>	Hamra, F.K., et al., "Uroguanylin: structure and activity of a second endogenous peptide that stimulates intestinal guanylate cyclase," <i>Proc. Natl. Acad. Sci. USA</i> , <b>1993</b> , <i>90</i> , 10464-10468
	<b>CX</b>	Hidaka, Y., et al., "Disulfide linkages in a heat-stable enterotoxin (Stp) produced by a porcine strain of enterotoxigenic escherichia coli," <i>Bull. Chem. Soc. Jpn.</i> , <b>1988</b> , <i>61</i> , 11265-1271
	<b>CY</b>	Ikemura, H., et al., "Heat-stable enterotoxin (ST <sub>h</sub> ) of human enterotoxigenic escherichia coli (Strain SK-1). Structure-activity relationship," <i>Chem. Soc. Of Jpn.</i> , <b>1984</b> , <i>57</i> (9), 2150-2156
	<b>CZ</b>	Ikemura, H., et al., "Synthesis of a heat-stable enterotoxin (ST <sub>h</sub> ) produced by a human strain SK-1 enterotoxigenic escherichia coli," <i>Chem. Soc. of Jpn.</i> , <b>1984</b> , <i>57</i> , 2543-2550
	<b>DA</b>	Kubota, H., et al., "A long-acting heat-stable enterotoxin analog of enterotoxigenic escherichia coli with a single D-amino acid," <i>Biochem. &amp; Biophys. Res.</i> , <b>1989</b> , <i>161</i> (1), 229-235

**EXAMINER****DATE CONSIDERED****RECEIVED**  
JUL 30 2003  
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**Form PTO-1449 Modified**

List of Patent and Publications  
Cited by Applicant  
(Use several sheets if necessary)

U.S. Department of Commerce  
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Group  
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**RECEIVED**  
 JUL 30 2003  
 TECH CENTER 1600/2000

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

<b>DB</b>	Shimonishi, Y., et al., "Mode of disulfide bond formation of a heat-stable enterotoxin (ST <sub>h</sub> ) produced by a human strain of enterotoxigenic escherichia coli," <i>Elsevier Science</i> , 1987, 215(1), 165-170
<b>DC</b>	Yoshimura, S., et al., "Essential structure for full enterotoxigenic activity of heat-stable enterotoxin produced by enterotoxigenic escherichia coli," <i>Elsevier Science</i> , 1985, 181(1), 38-142
<b>DD</b>	Yoshimura, S., Chemical synthesis of a heat-stable enterotoxin produced by enterotoxigenic escherichia coli strain 18D," <i>Chem. Soc. Jpn.</i> , 1984, 125-133
<b>DE</b>	Yoshimura, S., et al., "A heat-stable enterotoxin of vibrio cholerae non-01: chemical synthesis, and biological and physicochemical properties," <i>Biopolymers</i> , 1986, 25, S69-S83
<b>DF</b>	Chabalgoity, et al., "Expression and immunogenicity of an echinococcus granulosus fatty acid-binding protein in live attenuated salmonella vaccine strains," <i>Infection and Immunity</i> , 1997, 65(60), 2402-2412
<b>DG</b>	Karem, et al., "Differential induction of carrier antigen-specific immunity by salmonella typhimurium live-vaccine strains after single mucosal or intravenous immunization of balb/c mice," <i>Infection and Immunity</i> , 1995, 63(12), 4557-4563
<b>DH</b>	O'Callaghan, et al., "Immune responses in balb/c mice following immunization with aromatic compound or purine dependent salmonella typhimurium strains," <i>Immunology</i> , 1990, 69(2), 184-189
<b>DI</b>	Mann, E.A., et al., "comparison of freceptors for escherichia coli heat-stable enterotoxin: novel receptor present in IEC-6 cells," <i>Am. J. Physiol.</i> , 1993, 264, G172-G178
<b>DJ</b>	Ceriani, R., et al., "Variability in surface antigen expression of human breast epithelial cells cultured from normal breast, normal tissue peripheral to breast carcinomas, and breast carcinomas," <i>Cancer Res.</i> , 1984, 44, 3033-3039
<b>DK</b>	Ceriani, R., et al., "Circulating human mammary epithelial antigens in breast cancer," <i>PNAS USA</i> , 1982, 79, 5420-5424
<b>DL</b>	Drewett, J., et al., "The family of guanylyl cyclase receptors and their ligands," <i>Endocrine Reviews</i> , 1994, 15(2), 135-162

**EXAMINER**

**DATE CONSIDERED**

**Form PTO-1449 Modified**

List of Patent and Publications  
Cited by Applicant  
(Use several sheets if necessary)

U.S. Department of Commerce  
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**November 28, 2000**

Group  
**Not Yet Assigned**

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

<b>DM</b>	Forte, L., et al., "Receptors and cGMP signalling mechanism for E. Coli enterotoxin in opossum kidney," <i>Am. J. Physiol.</i> , Nov. 1988, 255 (5 pt. 2), F1040-F1046
<b>DN</b>	Forte, L., et al., "Escherichia coli enterotoxin receptors: localization in opossum kidney, intestine, and testis," <i>Am. J. Physiol.</i> , Nov. 1989, 257 (5 pt. 2), F874-F881
<b>DO</b>	Fischmann, A.J., et al., "A ticket to ride: peptide radiopharmaceuticals," <i>J. Nucl. Med.</i> , 1993, 34(12), 2253-2263
<b>DP</b>	Guerrant, R., et al., "Activation of intestinal guanylate cyclase by heat-stable enterotoxin of escherichia coli: studies of tissue specificity, potential receptors, and intermediates," <i>J. infect. Dis.</i> , Aug. 1980, 142(2), 220-228
<b>DQ</b>	Hardingham, J.E., et al., "Immunobead-PCR: A technique for the detection of circulating tumor cells using immunomagnetic beads and the polymerase chain reaction," <i>Cancer Res.</i> , Aug. 1, 1993, 53, 3455-3458
<b>DR</b>	Krause, W., et al., "Autoradiographic demonstration of specific binding sites for E. Coli enterotoxin in various epithelia of the North American Opossum," <i>Cell Tissue Res.</i> , 1990, 260, 387-394
<b>DS</b>	Lima, A., et al., "The effects of escherichia coli heat-stable enterotoxin in renal sodium tubular transport," <i>Pharmacology &amp; Toxicology</i> , 1992, 70, 163-167
<b>DT</b>	Rao, M., et al., "Mode of action of heat-stable escherichia coli enterotoxin tissue and subcellular specificities and role of cyclic GMP," <i>Biochimica et Biophysica Acta</i> , 1980, 632, 35-46
<b>DU</b>	Schulz, S., et al., "Cloning and expression of guanylin," <i>The J. of Biol. Chem.</i> , 1992, 267(23), 16019-16021
<b>DV</b>	Waldman, et al., "Influence of a glycine or proline substitution on the functional properties of a 14-amino-acid analog of escherichia coli heat-stable enterotoxin," <i>Infection and Immunity</i> , 1989, 57, 2420-2424
<b>DW</b>	White, A., et al., "Opossum kidney contains a functional receptor for the escherichia coli heat-stable enterotoxin," <i>Biochemical and Biophysical Res. Comm.</i> , 1989, 159(1), 363-367

**EXAMINER****DATE CONSIDERED**



**Form PTO-1449 Modified**Docket No.  
**TJU-2444**Serial No.  
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Patent and Trademark OfficeFiling Date  
**November 28, 2000**Group  
**Not Yet Assigned****OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

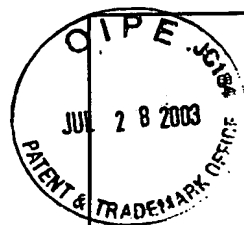
<b>DX</b>	Franz, et al., "The production of <sup>99m</sup> Tc-labeled conjugated antibodies using a cyclam-based bifunctional chelating agent," <i>J. Nucl. Med. Biol.</i> , <b>1987</b> , <i>14</i> , 569-572
<b>DY</b>	Bailey's Textbook of Histology, 16 <sup>th</sup> Ed., Coperhaven, et al., Williams and Wilkens, Baltimore, MD, <b>1975</b> , page 404
<b>DZ</b>	Wide, "Solid phase antigen-antibody systems," Radioimmunoassay Methods, Kirkham, (ed.), E & S, pages 405-412, Livingstone, Edinburgh, <b>1971</b>
<b>EA</b>	Beck-Sickinger, et al., "Neuropeptide Y: identification of the binding site," <i>Int. J. Peptide protein Res.</i> , <b>1990</b> , <i>36</i> , 522-530
<b>EB</b>	Blond-Elguindi, S., et al., "affinity panning of a library of peptides displayed on bacteriophages reveals the binding specificity of BiP," <i>Cell</i> , <b>1993</b> , <i>75</i> , 717-728
<b>EC</b>	Cull, M., et al., "Screening for receptor ligands using large libraries of peptides linked to the C terminus of the lac repressor," <i>PNAS USA</i> , <b>1992</b> , <i>89</i> , 1865-1869
<b>ED</b>	DeVita, V., "Principles of cancer therapy," in "Harrison's Principles of Internal medicine," McGraw-Hill, New York, <b>1983</b> , 765-787
<b>EE</b>	Fodor, S., "Light-Directed, spatially addressable parallel chemical synthesis," <i>Science</i> , <b>1991</b> , <i>251</i> , 767-773
<b>EF</b>	Forte, L., et al., "Guanylin: a peptide regulator of epithelial transport," <i>The FASEB Journal</i> , <b>1995</b> , <i>9</i> , 643-650
<b>EG</b>	Gallop, M., et al., "Applications of combinatorial technologies to drug discovery. 1. Background and peptide combinatorial libraries," <i>J. medicinal Chem.</i> , <b>1994</b> , <i>37</i> (9), 1233-1251
<b>EH</b>	Gordon, E., et al., "Applications of combinatorial technologies to drug discovery. 2. Combinatorial organic synthesis, library screening strategies, and future-directions," <i>J. medicinal Chem.</i> , <b>1994</b> , <i>37</i> (10), 1385-1401
<b>EI</b>	Hammer, J., et al., "Promiscuous and allele-specific anchors in HLA-DR-Binding peptides," <i>Cell</i> , <b>1993</b> , <i>74</i> , 197-203

**EXAMINER****DATE CONSIDERED**



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. <b>TJU-2444</b>	Serial No. <b>09,724,983</b>
		Applicant <b>Scott A. Waldman</b>	
		Filing Date <b>November 28, 2000</b>	Group <b>Not Yet Assigned</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>EJ</b>	Kita, T., et al., "Characterization of human uroguanylin: a member of the guanylin peptide family," <i>Amer. J. Physiol.</i> , <b>1994</b> , <i>266</i> , F342-F348	
	<b>EK</b>	Ohlmeyer, M., et al., "Complex synthetic chemical libraries indexed with molecular tags," <i>PNAS USA</i> , <b>1993</b> , <i>90</i> , 10922-10926	
	<b>EL</b>	Ostresh, J., et al., "'Libraries from libraries': Chemical transformation of combinatorial libraries to extend the range and repertoire of chemical diversity," <i>PNAS USA</i> , <b>1994</b> , <i>91</i> , 11138-11142	
	<b>EM</b>	Paxton, R., et al., "High-specific-activity <sup>111</sup> I-labeled anticarcinoembryonic antigen monoclonal antibody: improved method for the synthesis of diethylenetriaminepentaacetic acid conjugates," <i>Cancer Res.</i> , <b>1985</b> , <i>45</i> , 5694-5699	
	<b>EN</b>	Tuggeri, Z., et al., "Inhibition of platelet function with synthetic peptides designed to be high-affinity antagonists of fibrinogen binding to platelets," <i>PNAS USA</i> , <b>1986</b> , <i>83</i> , 5708-5712	
	<b>EO</b>	Sepetov, N., et al., "Library of libraries: approach to synthetic combinatorial library design and screening of "pharmacophore" motifs," <i>PNAS USA</i> , <b>1995</b> , <i>92</i> , 5426-5430	
	<b>EP</b>	Smith, G., et al., "A ribonuclease S-peptide antagonist discovered with a bacteriophage display library," <i>Gene</i> , <b>1993</b> , 37-42	
	<b>EQ</b>	Tucker, K., et al., "Covalent attachment of chelating groups to macromolecules," <i>Biochem. And Biophys. Res. Comm.</i> , <b>1977</b> , <i>77</i> (2), 581-585	
	<b>ER</b>	Vandraager, A., et al., "Guanylyl cyclase C is an N-linked glycoprotein receptor that accounts for multiple heat-stable enterotoxin-binding proteins in the intestine," <i>The J. biol. Chem.</i> , <b>1993</b> , <i>268</i> (3), 2174-2179	
	<b>ES</b>	Wang, et al., "Application of the multipin peptide synthesis technique for peptide receptor binding studies: substance P as a model system," <i>Bioorg. &amp; Med. Chem. Lett.</i> , <b>1993</b> , <i>3</i> , 447-450	
	<b>ET</b>	Zuckermann, R., et al., "Discovery of nanomolar ligands for 7-transmembrane G-protein-coupled receptors from a diverse N-(substituted)glycine peptoid library," <i>J. Med. Chem.</i> , <b>1994</b> , <i>37</i> , 2678-2685	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

**RECEIVED**  
JUL 30 2003  
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**Form PTO-1449 Modified**

List of Patent and Publications  
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**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	<b>EU</b>	5,160,723	11/03/92	Welt, et al.	424	1.69
	<b>EV</b>	4,584,268	04/22/86	Ceriani et al.	435	7
	<b>EW</b>	5,237,051	08/17/93	Garbers et al.	530	350
	<b>EX</b>	5,518,888	05/21/96	Waldman	435	7.23
	<b>EY</b>	5,601,990	02/11/97	Waldman	435	7.23
	<b>EZ</b>	4,341,763	07/28/82	Zygraich		
	<b>FA</b>	5,593,825	01/14/97	Carmen, e t al.		
	<b>FB</b>	5,087,616	02/11/92	Myers, A.E., et al.	514	21
	<b>FC</b>	5,443,816	08/22/95	Zamora, P.O., et al.	424	1.69
	<b>FD</b>	4,659,666	04/21/87	May, K., et al.	435	188
	<b>FE</b>	5,879,656	03/09/99	Waldman	424	149
	<b>FF</b>	5,731,159	03/24/98	Waldman	435	7.9
	<b>FG</b>	6,060,037	04/09/00	Waldman	424	1.65
	<b>FH</b>	4,683,195	07/28/87	Mullis, et al.	435	6
	<b>FI</b>	4,683,202	07/28/87	Mullis	435	91
	<b>FJ</b>	4,965,188	10/28/90	Mullis, et al.	435	6
	<b>FK</b>	5,075,216	12/24/91	Innis, et al.	435	6

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation YES NO	
	<b>FL</b>	83/9512	12/21/83	South Africa		
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>		

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JUL 30 2003  
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**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	<b>FM</b>	5,324,483	06/28/94	Cody, et al.	422	131
	<b>FN</b>	5,338,665	08/16/94	Schatz, et al.	435	6
	<b>FO</b>	5,340,474	08/23/94	Kauvar	210	198.2
	<b>FP</b>	5,366,382	11/22/94	Venton, et al.	435	7.1
	<b>FQ</b>	5,384,261	01/24/95	Winkler, et al.	436	518
	<b>FR</b>	5,395,750	03/07/95	Dillon, et al.	435	5
	<b>FS</b>	5,405,783	04/11/95	Pirrung, et al.	436	518
	<b>FT</b>	5,412,087	05/02/95	McGall, et al.	536	24.3
	<b>FU</b>	5,420,328	05/30/95	Campbell	558	110
	<b>FV</b>	5,424,186	06/13/95	Fodor, et al.	435	6
	<b>FW</b>	5,000,935	03/19/91	Faulk	424	1.69
	<b>FX</b>	4,867,973	09/19/89	Goers, J., et al.	424	85.91
	<b>FY</b>	4,963,263	10/16/90	Kauvar	210	635
	<b>FZ</b>	5,133,886	07/28/92	Kauvar	210	635
	<b>GA</b>	5,143,854	09/01/92	Pirrung, et al.	436	518
	<b>GB</b>	5,217,869	06/08/93	Kauvar	435	7.9
	<b>GC</b>	5,221,736	06/22/93	Coolidge, et al.	536	25.31
	<b>GD</b>	5,223,409	06/29/93	Ladner, et al.	435	69.7
	<b>GE</b>	5,252,743	10/12/93	Barrett, et al.	548	303.7
	<b>GF</b>	5,270,170	12/14/93	Schatz, et al.	435	7.37
	<b>GG</b>	5,288,514	02/22/94	Ellman	427	2
	<b>GH</b>	5,962,220	10/05/99	Waldman	435	6

**EXAMINER****DATE CONSIDERED**